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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,776	12/17/2004	Hideaki Sasagawa	TOYA107.005APC	5644

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EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

NOTIFICATION DATE	DELIVERY MODE
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07/27/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/518,776	Applicant(s) SASAGAWA ET AL.	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6,8-12 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6,8-12 and 15-18 is/are rejected.
- 7) ☐ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/16/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments filed March 24, 2009 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1, 4, 6, 8-12 and 15-19 are pending in this application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on January 16, 2009 has been considered by the examiner with the exception of the WO/97/02821 reference which has already been cited by the Examiner in the office action dated December 24, 2008. Consequently since this reference has already been considered and is of record, the citation on the 1449 has been lined out.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 6, 8-12 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al. WO 97/02821 A2 and JP 7 277975 (machine translation provided) and Sawyer U.S. Patent No. 6,403,063 B1.

The claims are drawn to a pharmaceutical composition comprising the antifungal agent of figures (1) and (2) combined with (A) a film forming agent selected from *inter alia*, ethyl cellulose and (B) a water soluble plasticizer in a form of a solid or a paste at 20°C (68°F or approximately normal room temperature) at 1 atm (normal atmospheric

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pressure) selected from a polymer or copolymer of oxyethylene and/or oxypropylene and has a polymerization degree of 70 or more.

JP 7 277975 teach an antifungal formulation comprising film forming agents selected from ethyl cellulose and hydroxypropylcellulose phthalate combined with plasticizers (see claim 1, page 1).

JP 7 277975 does not teach the specific antifungal agents and the specific plasticizers.

Kodama et al. teach the antifungal agents in figures (1) and (2) (see entire document). It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezei* 158 USPQ 99; the express suggestion to substitute the antifungal composition of Kodama et al. for the antifungal of JP 7 277975 need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532.

Regarding the plasticizers recited, Sawyer teaches the composition for treating nail fungus comprising an antifungal agent and a plasticizer (column 20, line 50). The plasticizer agent, oxyethylene oxypropylene copolymer is recited (column 13, line 39). The reaction mixture treats onychomycosis (columns 1-2) (mycosis of the nails resulting in thickened nails) by penetrating the thickened nail (addressing the limitations of instant claim 17) to polymerize to form a polyurea therapeutic coat on the treated nail (column 16, line 59 to column 17, line 7). The film or coat is solid at room temperature and at normal atmospheric pressure. Addressing claims 9-11, wetting agents are disclosed

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(surfactants) such as the alkyl sulfate, anionic, surfactant, sodium dioctyl sulfosuccinate (column 25, lines 55-67). Addressing instant claim 15 wherein the antifungal medicinal composition is capable of recoating, Sawyer teaches that the stabilized reaction solution is applied to the nail topically *to form a liquid film of a desired thickness* (column 22, lines 25-27). Addressing instant claim 16, drawn to the composition that is removable by inter alia, physical scratching, Sawyer teaches a composition that is likened to a nail polish or lacquer. It is well known that nail polish or nail lacquer can be removed by physical scratching.

The medicinal antifungal coating composition having a plastic property when applied to the target (medicinal nail polish) is known in the art by the teachings of Sawyer and film forming topical agent as disclosed in JP7 277975.

One of ordinary skill in the art could have substituted the antifungal agent of Sawyer and JP7 277975 for the antifungal agents of Kodama et al, and the results of the substitution would have been predictable. It would have been prima facie obvious to substitute the antifungal agent of Kodama for the antifungal agent of either Sawyer or JP7 277975. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious.

The prior art showed that onychomycosis is successfully treated with a film forming antifungal agent with a plasticizer and film forming agent and further comprising a surfactant. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the antifungal agents taught in Kodama et al for the antifungals of JP7 277975 or Sawyer for the predictable result of forming an antifungal medication that

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forms a film on the affected area so that it does not wash away easily. Addressing the limitations of instant claim 18, drawn to the method of producing an antifungal medicinal composition, "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983).

Regarding the degree of polymerization of the polymer or copolymer of oxyethylene and/or oxypropylene having 70 or more of polymerization degree, Sawyer teaches the composition for treating nail fungus comprising an antifungal agent and a plasticizer (column 20, line 50). The plasticizer agent, oxyethylene oxypropylene copolymer is recited (column 13, line 39). It does not teach the degree of polymerization of the copolymer. As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional

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limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Allowable Subject Matter

Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's remarks regarding the foreign priority have been noted. Regarding the oxyethylene oxypropylene copolymer as a plasticizer, Applicant asserts that the oxyethylene oxypropylene copolymer of Sawyer has low solubility because of the hydroxyl groups at both ends of the copolymer are protected with aminobenzoate which is hydrophobic. In response, the claim is drawn to a water soluble plasticizer that is a polymer or copolymer of oxyethylene and/or oxypropylene. Although the solubility is

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low, it is not insoluble. Applicant further states that Sawyer et al. does not obviate the instant claims because the claim is drawn to the coating film being in a viscous glass state. In response, a "viscous glass state" according to the specification, is in the form of a solid (page 18 of instant specification). The composition of Sawyer et al. forms a solid. Regarding the condition that the "components move inside the film", as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

July 20, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614